510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY TEMPLATE

A. 510(k) Number:
k060620

B. Purpose for Submission:
Modification of current blood glucose monitoring system

C. Measurand:
Glucose, home glucose monitoring test

D. Type of Test:
Quantitative

E. Applicant:
Roche Diagnostics

F. Proprietary and Established Names:
ACCU-CHEK Aviva glucose monitoring system

G. Regulatory Information:
1. Regulation section:
   21 CFR §862.1345, Glucose Test System
2. Classification:
   Class II
3. Product code:
   LFR, NBW
4. Panel:
   Clinical Chemistry (75)

H. Intended Use:
1. Intended use(s):
   See Indications for Use below.
2. Indication(s) for use:
   The ACCU-CHEK Aviva Test Strips are used with the ACCU-CHEK Aviva meter. The ACCU-CHEK Aviva test system is designed to quantitatively measure the concentration of glucose for monitoring glucose in the home or in health care facilities. Testing sites include traditional fingertip site along with palm, forearm, upper arm, thigh, and calf.

   Professionals may use the test strips to test capillary, venous, arterial, and neonatal blood; home use is limited to capillary whole blood testing.

3. Special conditions for use statement(s):
   Provides plasma equivalent results.
   For over-the-counter use (capillary only) or professional use.

4. Special instrument requirements:
   None; this is a complete blood glucose monitoring system (ACCU-CHEK Aviva glucose monitoring system).

I. Device Description:

The ACCU-CHEK Aviva system utilizes reagent test strips stored within a desiccated vial. A test strip is removed from the vial and inserted into the meter. Upon insertion, the meter is activated. Blood is applied to the end of the test strip and a glucose result is reported. The ACCU-CHEK Aviva system includes:

- ACCU-CHEK Aviva meter with battery
- ACCU-CHEK test strips and code key (may be sold separately)
- ACCU-CHEK Aviva control solutions (may be sold separately)
- ACCU-CHEK Multiclix lancet device (with blue cap for fingertip testing and a clear cap for non-fingertip testing)
- ACCU-CHEK Multiclix lancets

J. Substantial Equivalence Information:

1. Predicate device name(s):
   ACCU-CHEK Aviva System
2. Predicate 510(k) number(s):
   k043474 – introduction of Aviva system: expanded lower limit of linearity, decreased sample volume compared to its predicate (k032552). Alternate site testing in k043474 used k022127 as a predicate.
3. Comparison with predicate:
   The device and the predicate are similar in the following ways: they have the same intended use and test principle, the same reagent composition, use the same blood volume, have the same operating principles, have the same reportable range, and the same reagent stability.

   The reviewed device differs in the allowed samples types (this submission adds arterial, neonatal capillary, and neonatal cord blood) and extends the hematocrit range of the meter to 10 – 70%.

K. Standard/Guidance Document Referenced (if applicable):

None referenced.

L. Test Principle:

The ACCU-CHEK Aviva System utilizes Glucose dehydrogenase technology. The enzyme glucose dehydrogenase converts the glucose in a blood sample to gluconolactone. This reaction liberates an electron that reacts with a coenzyme electron acceptor, the oxidized form of the mediator hexacyanoferrate (III), forming the reduced form of the mediator hexacyanoferrate (III). The test strip employs the

electrochemical principle of biamperometry. The meter applies a voltage between two identical electrodes, which causes the reduced mediator formed during the incubation period to be reconverted to an oxidized mediator. This generates a small current that is read by the meter and reported as the glucose result.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

   a. Precision/Reproducibility:
   Established in k043474.

   b. Linearity/assay reportable range:
   Studies were performed in k043474; the assay range is 10 – 600 mg/dL

   c. Traceability, Stability, Expected values (controls, calibrators, or methods):
   Controls were cleared under k043474.

   d. Detection limit:
   Established in k043474.

   e. Analytical specificity:
   A study was performed to determine if the lower limit of the hematocrit range could be extended from 20% to 10%. ACCU-CHEK Aviva meter results from spiked low (~40 mg/dL), normal (~120 mg/dL), and high (~450 mg/dL) blood samples adjusted to a hematocrit of 10% were compared to results for low, normal, and high spiked samples with a hematocrit of 43%. Three strip lots were tested 16 times each for a total of 48 replicates per condition. Bias compared to the normative hematocrit was within acceptable limits.

   Other analytical specificity parameters were established in k043474. The following will be claimed as limitations for potential interference:
   - Galactose
   - Lipidemia (Triglycerides)
   - Maltose
   - Xylose (Xylose was not be tested in whole blood but will be listed as a limitation based on serum results.)

   These compounds, in excess of the concentrations below, may produce elevated results:
   - Galactose: >10 mg/dL can give falsely elevated test results.
   - Maltose: >13 mg/dL intravenously can give falsely elevated test results.
   - Lipids (Triglycerides) : >4800 mg/dL can give falsely elevated test results

   f. Assay cut-off:
   Not applicable.

2. Comparison studies:

a. *Method comparison with predicate device:*
Capillary fingerstick (i.e. consumer testing) testing, venous, and alternate site testing claims were established in k043474.

b. *Matrix comparison:*
Arterial samples: One hundred ninety-seven (197) random arterial samples from 2 hospital sites were collected and tested on three different strip lots with the ACCU-CHEK Aviva meter and compared to a reference laboratory glucose hexokinase method (tested in duplicate) converted to a plasma equivalent value. Samples ranged from 37 – 489 mg/dL; hematocrits ranged from approximately 10 – 51%. Mean bias (units = mg/dL at glucose concentrations < 75mg/dL % at glucose concentrations ≥75 mg/d), the percentage of results that fall outside of the sponsor's acceptance criteria (the percentage of individual results falling outside 15 mg/dL of the reference result at glucose concentrations < 75mg/dL and outside 20% of the reference at glucose concentrations ≥75 mg/dL will not be significantly higher than 5%), and regression analysis were calculated for each lot:

ACCU-CHEK Aviva Arterial Glucose Sample Performance

Lot #	Regression	Correlation	Mean Bias	% Outliers
1	y = 0.983 – 0.2	0.983	-2	1
2	y = 0.998 + 0.4	0.983	0	2
3	y = 0.990 + 4.3	0.981	2.2	2.5

Neonate capillary samples: Ninety-six (96) capillary heelstick samples were collected from one clinical site; all samples were from subjects less than 31 days old. Each sample was tested on three different strip lots with the ACCU-CHEK Aviva meter and compared to a reference laboratory glucose hexokinase method (tested in duplicate) converted to a plasma equivalent value. Samples ranged from 13 – 432 mg/dL; hematocrits ranged from 27 – 67%. Approximately one-third of the samples had glucose values less than 50 mg/dL; four samples were above 150 mg/dL. Mean bias (units = mg/dL at glucose concentrations < 75mg/dL % at glucose concentrations ≥75 mg/d), the percentage of results that fall outside of the sponsor's acceptance criteria (the percentage of individual results falling outside 15 mg/dL of the reference result at glucose concentrations < 75mg/dL and outside 20% of the reference at glucose concentrations ≥75 mg/dL will not be significantly higher than 5%), and regression analysis were calculated for each lot:

ACCU-CHEK Aviva Neonatal Glucose Sample Performance

Lot #	Regression	Correlation	Mean Bias	% Outliers
1	y = 0.960 + 3.1	0.987	-0.9	4.2
2	y = 0.977 + 2.8	0.986	-1.1	5.2
3	y = 0.959 + 5.9	0.984	1.6	5.2

Since the neonatal clinical samples did not cover the claimed meter range, results from a study of accuracy of spiked samples with extremely high glucose concentrations and varying hematocrits were provided by the sponsor to demonstrate acceptable performance (≤ 20 % bias from laboratory reference) at the upper end of the claimed range. These laboratory results were not incorporated into the clinical study data presented above or in the labeling.

3. Clinical studies:
   a. Clinical Sensitivity:
   Not applicable.
   b. Clinical specificity:
   Not applicable.
   c. Other clinical supportive data (when a. and b. are not applicable):

4. Clinical cut-off:
   Not applicable.

5. Expected values/Reference range:
   The normal fasting blood glucose range for an adult without diabetes as related to plasma is 74-106 mg/dL[1]. Two hours after meals, blood glucose range for a non-diabetic is less than 140 mg/dL[2]. For people with diabetes please consult your diabetes team for the blood glucose range appropriate for you.

   1. Stedman, TL, Stedman's Medical Dictionary, 27th Edition, 1999, p. 2082.
   2. American Diabetes Association, Clinical Practice Recommendation Guidelines 2003, Diabetes Care, Vol. 26. Supplement 1, p. S22.

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10..

O. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.